toXcel

Toxicology & Regulatory Affairs 7140 Heritage Village Plaza Gainesville, VA 20155-3061

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HAND DELIVERED

August 2, 2017

Mr. Demson Fuller (PM-32)
Antimicrobial Division
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501



RE:

Efficacy Data and Label Amendment for Sodium Chlorite Technical and Notification of Alternative Trade Name, CD Generation Part "A" EPA File Symbol 90094-1

Dear Mr. Fuller:

On behalf of DRS Laboratories, Inc., we are submitting the enclosed efficacy study and label amendment for "Sodium Chlorite Technical", which contains the active ingredient Sodium chlorite at 80%. (Registration No. 90094-1)

The efficacy study was conducted using a protocol that was reviewed and deemed adequate by the EPA in their initial review and subsequent letter, both dated July 2015. The protocol was designed to determine the efficacy of the product when used as a sterilant/decontaminant in confined areas.

As required, the following documentation has been provided:

- 1. Amendment Application (EPA Form 8570-1)
- 2. Small Business Fee Waiver documentation
- 3. PRIA Payment Confirmation
- 4. Labeling (Master label and Mini-CD System® Instruction Manual)
- 5. Courtesy copy of the safety data sheet and labeling for Solid Component "B", which is referenced but is not a FIFRA regulated product
- 6. Labeling (Master and Instruction Manual) One (1) electronic copy
- 7. Certification with Respect to Label Integrity
- 8. Efficacy volume supporting the proposed additional use

Mr. Demson Fuller August 2, 2017 Page 2 of 2

It is our understanding that this label amendment application will be processed under PRIA category A570, label amendment requiring study review, in a timeframe of four (4) months.

If you have any questions or require additional information, please contact me by email at melba.morrow@toxcel.com or by phone at 703-754-0248 x8120.

Sincerely,

Melba S. Morrow, DVM

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Representative for DRS Laboratories, Inc.

Director of Toxicology, toXcel, LLC

Enclosures

CC: Mike Regits (DRS Labs)

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

DRS Laboratories, Inc. P.O. Box 20247

Lehigh Valley, PA 18002

Authorized Representative

toXcel, LLC

7140 Heritage Village Plaza

Gainesville, VA 20155

2. Regulatory Action

Label Amendment and Alternate Trade Name EPA Reg. No. 90094-1

3. Transmittal Date

2 August 2017

4. List of Submitted Studies/Documents

Admin

- EPA Form 8570-1 Application for Registration
- Proposed Draft Label (5 paper copies, 1 electronic)
- · Certification with Respect to Label Integrity
- PRIA Payment Receipt
- Small Business Waiver

MRID 50344501

Volume 1

Study to Support the Use of EPA Reg. No. 90094-1 with the Mini Chlorine Dioxide System (MCS) to Sterilize/Decontaminate Confined Areas, Specifically Including Biological Safety Cabinets. December 7, 2016; DRS Laboratories Inc. and Azzur Labs LLC; Azzur Labs Laboratory Project Number 170939;

810.2100; 222 pages.

Company Name/Representative:

Company Name: I

DRS Laboratories, Inc.

Authorized Representative:

Melba Morrow, DVM

2 August 2017

Date

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